IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH

CENTRAL DIVISION

JOHN T. BRAUN, M.D.,)

Plaintiff,)

vs.) CASE NO. 2:10-CV-1283RS

MEDTRONIC SOFAMOR DANEK, INC.,)

Defendant.)

_____)

BEFORE THE HONORABLE ROBERT J. SHELBY

February 19, 2014

Jury Trial

Volume I

A P P E A R A N C E S

For Plaintiff:
ALAN BRADSHAW
CHAD R. DERUM
136 East South Temple
Suite 1300
Salt Lake City, Utah

ROGER DODD
3319 America Saddler Drive
Park City, Utah

For Defendant:
JAMES JARDINE
JOHN ADAMS
RYAN BELL
GREG NEWMAN
36 South State Street
Suite 1400
Salt Lake City, Utah

Court Reporter:
Ed Young
Rebecca Janke
Laura Robinson
Patti Walker
247 U.S. Courthouse
350 South Main Street
Salt Lake City, Utah 84101-2180
801-328-3202

I N D E X

Exhibit	Received

February 19, 2014 8:30 a.m.

P R O C E E D I N G S

THE COURT: We'll call Braun vs. Medtronic, 2:10-CV-1283. We're on the record.

Good morning, everyone.

Just a couple of matters. First, we received your objections to the proposed jury instructions, at least Dr. Braun's, and we have reviewed those this morning and they look perfect, like exactly what we had in mind by way of format. Thank you.

Medtronic, we just have not looked at yours yet, but I am sure they are fine.

Also, we entered this morning the trial order. It may not be on the docket yet, but we signed and entered that. Thank you for your work on that.

I think you have trial notebooks for the jurors. Counsel, did you have in mind that you wanted the jurors to have those during your openings or afterwards?

MR. JARDINE: I think afterwards, Your Honor. We are fine with that.

MR. BRADSHAW: That is fine, Your Honor.

THE COURT: We'll do that.

I wanted to give you rulings on the last few evidentiary issues that we had last night, and I appreciate

you bringing them to our attention, even if we were all a little punch drunk after a long day yesterday.

Let's do this quickly and get the jury in here. I'm looking at Mr. Pafford's deposition testimony. There were objections raised to the proposed testimony beginning at page 63 over to 66, and also beginning on page 75 and over to page 77, and then continuing again on 79 to 81. Let me take up those three segments first.

I'm going to sustain the objections. In my view the deposition testimony that is proposed here is irrelevant to the issues in dispute. There is a question in this case, in my mind, about the date of conception and ownership of Dr. Braun's invention, but it relates entirely to his service at the Air Force and issues that came to light many years after the fact. What Medtronic believed was necessary for conception or the date of conception under its own policies and practices in 1999 and 2000 I think are wholly irrelevant.

I also think that if Dr. Braun wanted to pursue Medtronic's contentions concerning those issues, that the proper format for that was to serve contention interrogatories or to provide a Rule 30(b)(6) area of inquiry in that regard, not to ask a fact witness after the fact.

Moreover, I'm concerned that the testimony is

riddled with legal conclusions and I think on whole, in light of the remote relevance, if any, and the risk of confusion or prejudice I'm going to sustain the objections to the testimony we just discussed.

On the other hand, the testimony that is provided on pages 89 to 91, I don't see that it is particularly helpful, and I am not sure what the relevance is, but I don't see that it is unusually prejudicial, and while there is I think a close call on foundation, it seems to me the witness can testify about that matter. We'll overrule the objection with respect to that last segment.

MR. DERUM: Can I just ask for one point of clarification? The Court addressed last night that there was a separate issue with respect to the testimony given at pages 80 to 81 where this witness, Mr. Pafford, who signed the license agreement, expresses an understanding about what the date of conception was for the license agreement. I just want to understand if the Court's ruling encompasses that, and --

THE COURT: It does. What a fact witness years after the fact thinks the date of conception of this invention is just by looking at it -- he has no idea. Dr. Braun knows the date of conception. This witness has no basis for that testimony. He can look at a document and see the date that is on it, and that is what he has testified

about here, but I think it lacks foundation in so far as it purports to be the testimony of a Medtronic employee about the date of Dr. Braun's conception.

I am sustaining the objection.

MR. DERUM: Very good, Your Honor. Thank you.

THE COURT: Is there anything more we should take up before we bring the jury in?

Mr. Jardine.

MR. JARDINE: Just one question, Your Honor. It would helpful if we could take a break between the openings to just set up and make sure our audiovisual is working. I don't know what you were planning.

THE COURT: Do you mean between the two opening statements?

MR. JARDINE: Yes, between Mr. Bradshaw's and mine. I think it will be about an hour, and --

THE COURT: I had had in mind that if the plaintiff's opening was on the order of an hour that we would give the court reporters a short break anyway before we get into the next opening. Let's do that. That is great.

MR. JARDINE: Thank you.

THE COURT: Anything more, counsel?

Ms. McNamee, let's bring the jury in.

MR. BRADSHAW: Your Honor, just a logistical

question for you.

THE COURT: Yes.

MR. BRADSHAW: We're going to use the screen, but we also have three foam boards, and I'm wondering if after the jury has filed in if we can put the easel in front of the witness chair and put one of the boards there, and then my assistant, if she can sit in the witness chair, she can change those out.

THE COURT: That is fine.

I forgot to ask whether any of you were intending to invoke the exclusionary rule and whether that would be relevant for openings.

MR. JARDINE: We do not, Your Honor.

THE COURT: All right.

MR. BRADSHAW: Yes, Your Honor.

THE COURT: I'm sorry?

MR. BRADSHAW: Yes, Your Honor, we would.

THE COURT: Is there anyone here on behalf of Medtronic, other than the client representatives who are at counsel table, that are witnesses in the case?

MR. JARDINE: I think that raises the issue of Mr. Horseman, who has been the supervising in-house lawyer that they have listed as a may-call.

THE COURT: Right.

MR. BRADSHAW: We have no objection to Mr.

Horseman remaining.

THE COURT: Mr. Horseman may remain.

MR. JARDINE: Your Honor, I'm being prompted to ask, does that include experts?

THE COURT: I don't believe it does.

Mr. Bradshaw?

MR. DERUM: Mr. Richter, as we know, is not just an expert. He is wearing a variety of hats.

THE COURT: He is offering expert testimony? He is, is he not? Doesn't he need to be present so that he has an opportunity to provide that testimony in the context of the other expert opinions that are provided?

MR. DERUM: That would be up to the party offering the testimony, but I am just raising the point that, as the Court knows, he is not only an expert. There are other factual matters.

THE COURT: Well, I am limiting his testimony in that regard and we talked about that. Mr. Richter may stay.

(WHEREUPON, the jury enters the proceedings.)

THE COURT: Good morning, members of the jury. You all look a little more fresh than you did when last we visited. It is good to see all of you.

Just a little housekeeping so that you have some idea what to expect by way of schedule. We spoke about this briefly yesterday, but it was early, and many of you

probably didn't really think you would be seated in those seats. We'll be going from about 8:30 in the morning until 5:00 each day. We'll take a 45-minute lunch break sometime around 11:45, so about every hour and a half or so. It is helpful for our court reporters to have a break to stretch their fingers, and I find that the attorneys like a chance to clear their heads, and it is not so bad for you folks either. So we'll take short 15-minute breaks about every hour and a half.

This morning we'll have opening statements, and we'll probably take a short break between the opening statements to change out some audiovisual and allow the court reporter to stretch a little bit. Then we'll sort of get into a more routine schedule after that. We will begin this morning with opening arguments.

Counsel, are you prepare to proceed?

MR. BRADSHAW: We are, Your Honor.

MR. JARDINE: We are as well, Your Honor.

THE COURT: Thank you.

Mr. Bradshaw, you have the floor.

MR. BRADSHAW: Thank you, Your Honor.

Your Honor, would you let us know if this unduly obstructs?

THE COURT: Don't worry about me. I'll be fine.

MR. BRADSHAW: Good morning, ladies and gentlemen.

I introduced myself yesterday. I am Alan Bradshaw and I am counsel for Dr. John Braun with my co-counsel, Chad Derum and Roger Dodd. Dr. Braun is seated here. Dr. Braun's wife, Cricket Braun, who was here yesterday, they have had a daughter who has had a potentially serious medical issue come up and she has had to go home. We're planning on bringing her back next week. That is the reason that she is not here.

I would like to talk to you about what the evidence is that you will see in this case. The evidence will show that Dr. Braun is an orthopedic spine surgeon who has essentially dedicated his career to helping children and adolescents with the treatment of scoliosis.

Now, scoliosis, as you may understand, is a serious spinal deformity that impacts approximately 25,000 to 30,000 children and adolescents in the United States each year. Scoliosis essentially has an indication in two different forms. One is what is called early onset scoliosis or EOS, which is basically children from zero to age nine. There is also something called adolescent idiopathic scoliosis or AIS, and I know in these medical cases the abbreviations are difficult, but I have put up on this board an indication of some of the different kinds of terms that you will be hearing in this case.

It is inevitable that the lawyers and the

witnesses will be using some of these terms. This is not designed to be a full definition. It is just designed to try to give you some kind of indication of what we're talking about and what area we are in.

With respect to AIS, which is what effects the ten to 18 year olds, for reasons that no one really understands it impacts girls five to seven times more often than it effects boys. The treatment for scoliosis for children and adolescents is a fusion surgery. No one in this case will dispute that a fusion surgery is a very serious and a very invasive surgery. It essentially involves the surgeon entering from the posterior, and that is another term that you're going to hear quite a bit, posterior and anterior, but it is a posterior application where the surgeon gets into the back of the spine and inserts two rigid rods, and hooks those rods with hooks and screws to the child or adolescent, and then the spine itself is fused. So the issue with the fusion surgery is that the child loses growth motion and function of the spine.

The defendant in this case is Medtronic Sofamor Danek. The evidence will show that Medtronic is one of four large manufacturers of medical devices including, and in particular, it is a manufacturer of fusion products. The evidence will show that Medtronic basically sells approximately 50 percent of the products that are used for

fusion surgeries in the United States.

Dr. Braun and Medtronic entered into a contract, which the Court has discussed with you, called a license agreement. That license agreement was effective April 1st of 2000. The license agreement includes an assignment by Dr. Braun to Medtronic of an invention that involves a fushionless treatment for adolescent idiopathic scoliosis, so for treating the young boys and girls age 10 to 18.

Now, the reason it is called fushionless is because it does not involve the fusing of the spine. I will get into more of the details of what it specifically does, but in a nutshell it involves using what is called a bone anchor, which goes into the vertebrae, that is then tethered with a flexible tether on one side of the spine and not the other side of the spine. The idea is that as the surgery is performed the surgeon can get a correction on the convex side of the Spain. This is the convex side, this side, as it is curved.

Then as the child grows and as the child goes through puberty you get additional correction because the side that is tethered with the flexible tether is restrained in its growth. The other side as the child grows continues to grow and you get additional straightening of the spine. You have essentially straightening during the surgery as well as as the child grows.

With respect to the fusionless treatment of scoliosis, the child continues to have the function and the growth and motion associated with their spine, rather than having to fuse those disks.

Now, you're going to hear some evidence about other fusionless products that Medtronic had in connection with its potential pursuit of a fusionless treatment for scoliosis. I would like to mention one of those. Again, in shorthand, there is something called a screw/tether, which essentially involves a Medtronic screw, rather than a bone anchor that Dr. Braun designed, but it also includes a flexible tether on the convex side of the spine.

They also had something called SMA staples, which were what they sound like, and they were staples that were used to staple the convex side of the spine as part of the operation, leaving the other side of the spine so that it could continue to grow.

Now, the license agreement that Dr. Braun entered into contains significant shall promises by Medtronic to Dr. Braun. We're going to look at those in considerable detail, but central to the evidence that you will hear is that Medtronic firmly promised that it shall in the contract do five things. One, that it would conduct research and development necessary to commercialize Dr. Braun's invention. Two, that it would prepare and execute a

development plan. Three, that it would file an application with the FDA, the Food and Drug Administration, and conduct human clinical trials if required by the FDA. The evidence will show that such human clinical trials were not only required by the FDA, but that Medtronic always, always knew that they would be required. The evidence will show that this single promise by Medtronic to conduct human clinical trials represents approximately a $30 million commitment to Dr. Braun and to the development of his device.

Medtronic also promised Dr. Braun that it shall provide worldwide marketing and distribution. Medtronic also agreed to use sound and reasonable judgment in obtaining patent protection for Dr. Braun's device. The evidence will prove quite clearly that Medtronic did not perform any of these contract promises as well as other contract promises.

The evidence will show, for example, that Medtronic put into the agreement as Exhibit B a projected development plan, which was a prediction of when Medtronic thought things would occur under this development plan. That development plan that was dated April 1st of 2000 was never changed, even though the agreement required that a subsequent plan be entered into and executed.

Human trials under that development plan in the agreement were projected to begin in April of 2002. In

reality, Medtronic has never sought from the FDA permission to do a human clinical trial, either with respect to Dr. Braun's anchor tether or with respect to Medtronic's screw/tether. They have never gone to the FDA from that time, from 2000 until now.

The evidence will show that Medtronic committed to prepare and execute a subsequent development plan. Medtronic never did so in the ten years between when the contract was signed in 2000 and when Dr. Braun brought this lawsuit in 2010. The evidence will show that the main thing that Medtronic did do was pay for animal studies by Dr. Braun. What they were doing was they were paying for Dr. Braun to conduct research on live goats. They were paying for the hardware associated with those studies, and they were paying for some of Dr. Braun's research assistants to work on those projects between 2000 and 2006. They were not separately compensating Dr. Braun for his time and effort in pursuing the animal studies.

The evidence will show that Medtronic's commitment was approximately a $275,000 commitment over a six-year period to do the animal studies. The evidence will show in context, that that $275,000 comes in the context of where Medtronic is projecting the cost of development of the device of Dr. Braun and the method that Dr. Braun had was $62 million to bring it to market.

You're going to hear substantial reasons why Medtronic refused to perform. The reason that you're going to hear evidence as to the why question, is because the reasons why Medtronic didn't perform the contract is relevant to other claims that Dr. Braun has brought in this case. Those claims include a claim for fraudulent inducement, inducing him to enter into the license agreement, and they also relate to claims related to the misappropriation of Dr. Braun's ideas and intellectual property into patents that Medtronic filed on its own behalf not naming Dr. Braun as an inventor.

The evidence that you will hear is that Medtronic didn't intend to perform its contract, because doing so is inconsistent with the way it does business and its business model. We're going to look at a number of documents that relate to the way they do business. The evidence will include that Medtronic simply does not make shall promises. It does not make promises consistent with those five commitments that it made to Dr. Braun in this case.

Medtronic normally commits to development, including things like FDA filings and the tens of millions of dollars in costs, only within its discretion and only if it chooses to proceed, but that is not the case with respect to Dr. Braun. The evidence will also show that Medtronic uses its contracts like it entered into with Dr. Braun to

try to keep surgeons within the Medtronic family. A surgeon like Dr. Braun, by himself, one individual surgeon, an orthopedic surgeon who is doing spinal surgeries, in a year can provide, the evidence will show, $1 million of profit to Medtronic by himself with respect to the particular products that he chooses to install within the patients who he treats.

You're also going to hear substantial evidence that Medtronic's firm commitment to Dr. Braun was inconsistent with its business plan and its way of doing business. The evidence of the business plan will reveal that while Medtronic always knew that a human clinical trial would be required by the FDA, Medtronic never intended to perform that promise and the extraordinary expense involved. The evidence will consist of documents, and the fact that even as of today Medtronic has never committed, funded or budgeted for the necessary FDA clinical trials with fusionless tethered devices.

Another example of the inconsistency between Medtronic's business model and the contract will be documentary evidence, that after promising Dr. Braun that it would pursue patent protection on his behalf, Medtronic filed and obtained a very limited patent on behalf of Dr. Braun covering the bone anchor, but not the surgical methods disclosed by Dr. Braun to Medtronic. What Medtronic did is

it consciously abandoned Dr. Braun's surgical methods, and the evidence will show that literally three weeks after abandoning those surgical methods on behalf of Dr. Braun, Medtronic filed a patent through its own employees listing that surgical method and not listing Dr. Braun as an inventor of that method.

The evidence of the planning documents will reveal Medtronic's business motivations. Specifically, the business plan was to develop a fusionless tether device if, and only if, Medtronic could do so without having to spend tens of millions of dollars on human clinical trials. The evidence will show that Medtronic was willing to pursue the fusionless tether devices only if it didn't put in jeopardy Medtronic's 50-percent share of the existing fusion surgeries that it was doing on children and adolescents, and only if it had a competitor who was ready to come into this area and take away its market share.

The evidence will show that Medtronic was not otherwise going to disrupt its approximately $200 million share of profits associated with fusion surgeries on children and adolescents. The evidence will reveal that in pursuing its business strategy Medtronic continued to buy up as many patents within the fusionless area as it could obtain.

I'm now going to discuss some of that specific

evidence, and I'm going to try to talk about it really in three pieces. I'm going to talk about the evidence of Medtronic's lack of effort to get regulatory approval from the FDA, and I'm going to talk about the evidence of their conduct in patenting for itself Dr. Braun's ideas, and I am going to talk about the overall lack of development of a commitment to what it promised in the license agreement.

Now, I'm going to ask you to pay particular attention to the exhibits that I identify and the exhibit numbers. The reason is is because there are parts of this story that you are only going to see and understand through Medtronic's business records. When you're presented with the opportunity to make a decision in this case, you're going to go back in the jury room and you're going to have a number of documents that you're going to have to look at, and you're going to have to make some decisions about what those documents mean and what they represent.

I want to try to talk about some of what that will be. After you have heard the evidence we'll come back and we'll have a chance to offer a closing argument and we'll, of course, go over some of that information again.

It is not unusual that a company's intentions and its plans would be found in its business records. That is where Medtronic's plans and way of doing business is disclosed. The evidence will show that Medtronic never

intended to fulfill its shall promises made to Dr. Braun. I would like to talk about some of the documents. The first one I want to talk about is Exhibit 96. This is a business plan that Medtronic prepared. In that plan Medtronic provides a short introduction about itself, and it says that the primary mission of Medtronic Sofamor Danek has been to provide spinal surgeons with comprehensive solutions to perform fusion of the vertebral bodies. Medtronic Sofamor Danek has been a dominant force in the introduction of many of these technologies and continues to be the number one player in the industry.

The evidence will show that by 1999 and 2000 Medtronic recognized that there may be a better way to treat children and adolescents with scoliosis. In this document Medtronic says that minimally invasive technologies have the potential to reduce trauma with therapeutic interactions, streamline recovery time and decrease overall treatment costs. At the forefront of all of this development is the adolescent non-fusion solutions for degenerative spinal pathologies.

This same business plan, Exhibit 96, reveals Medtronic's business strategy of buying up as much of the fusionless technology as it can. Medtronic says in general we have a two-pronged approach to protecting our fusionless scoliosis project. We have filed and received a number of

patents on the general concept of tethering the convex side of the curve without fusing the spine. This is a comprehensive portfolio in the area of fusionless scoliosis correction and should provide broad protection. We have also filed and continue to file device specific applications.

You will hear testimony from Medtronic's current vice president of research and development, a gentleman by the name of Tommy Carls, that in general Medtronic's patent and intellectual property strategy is to buy technology, and sometimes the word he uses is offensively to actually develop something, but sometimes it is bought to bring value to the company by protection against competitors.

The evidence will show that Medtronic at the time of its contract with Dr. Braun and thereafter always recognized the impact that a fusionless surgery would have on its sale of fusion products. I would like to have you take a look at Exhibit 295, which is a July 7, 2006 fusionless scoliosis market assessment. This is hard to read, but what it basically says is that 75 percent of the procedures that will be performed for fusionless are not going to come from a new market or new patients. They will be the replacements of existing fusion procedures. So up here in this document they have the 75 percent and they call it net of cannibalization, and cannibalization is another

form we have put up here, and it is a Medtronic word, and basically what it means is that those are sales of fusionless products that would come from fusions. So 75 percent would come from the fusion sales.

In other words, according to this document, which shows a net profit figure of $61 million, net of cannibalization for Medtronic's projection at that time, that means that 133 million is coming from cannibalized sales. That is the market that Medtronic, the evidence will show, has an incentive to protect.

If we look at Exhibit 113, which is another important document, again, this is a fusionless project update and this is much earlier. This is March 27th of 2001. In that document Medtronic again is looking at how much fusionless is going to come from fusion. They have 129 million, 147 million and 161 million in 2000 to 2002.

Now, the evidence will also put in context the cost of developing a fusionless device. At the time Medtronic made its shall promises to Dr. Braun it understood, the evidence will show, that it is a very expensive proposition involving, inevitably, human clinical trials. Exhibit 332 is a 2009 document that relates to Medtronic's projections at that time with respect to fusionless. In that document Medtronic is indicating that the development costs associated with fusionless are $62

million. That is the top, up here at the very top.

The other thing that they indicate is that the required needs include IDE funding. Again, that is another one of those funny acronyms that you're going to hear more than you care to hear about. What that is is that is a FDA reference to something called an investigational device exemption. That is the filing that you make with the FDA to get permission to do a human clinical trial.

I would now like to talk about the license agreement, which is obviously a document that is at the center of this case, and I would like to talk about the shall promises that were made to Dr. Braun on April 1st of 2000. This is the license agreement. Now, it has a number of components. Attached to the license agreement as an exhibit, and you'll have a copy of this document, is Dr. Braun's invention and his invention disclosure. I would like to talk a little bit about the invention and its components.

Again, Dr. Braun was proposing a minimally invasive approach anteriorly, and it really is not so much straight on, it is more from the side through the ribs, and it is done with an endoscope as opposed to having to open up the back. It includes a bone anchor, which is this device at the top left, which is the item that is put into the vertebrae as part of the surgery.

Now, that bone anchor has something, and this is another funny word, something called frustoconical, which basically what that means is just that it is shaped like an ice cream cone where someone bit off the bottom of the ice cream cone. It is hollow. It also has something called fenestrations, which are essentially like a cheese grater, so that as the bone anchor is put into the vertebral body, the idea is that you have bone matter inside of that hollow chamber that then grows inside of the chamber and comes out of the chamber through the fenestration so that you get real fixation with the vertebral body.

Dr. Braun then discloses on pages 7 through 10 of his disclosure a corrective maneuver. This is a surgical method for correcting scoliosis without fusion. What he describes is that these bone anchors that are fixed in the vertebrae are then compressed together so that you're getting a correction of the scoliosis on the table, and while those bone anchors are compressed you attach the flexible tether so that you obtain the correction right there on the table.

Now, the correction maneuver also describes that as the surgeon has obtained correction of the scoliosis, if he needs to dial in that correction he can use crimps around the flexible tethers to get additional compression of the vertebral bodies to get the correction exactly where the

surgeon wants it to be.

Now, the invention also involves, as I have described before, this notion of -- well, let me say one thing, which is that Dr. Braun will describe that this surgical method, his shorthand for that is something called active correction. Now, active correction is just that. It is a shorthand. It is a way to try to describe the surgical method in a few words.

The invention also discloses what we will call in shorthand passive correction, which is, again, this idea that if you flexibly constrain one side of the spine, that side of the spine will not grow, and the other side of the spoon will continue to grow, and as the child grows you get additional correction of the spinal curvature.

Now, in looking at the license agreement, this is where the shall promises are contained. What it indicates is that Medtronic shall be responsible at its own expense for the following tasks set forth in the development plan. A, prepare and execute a development work plan in accordance with the proposed development plan set forth in Exhibit B. We're going to look at that development plan in Exhibit B. The second part, B, prepare, file and conduct an investigational device exemption, IDE, with the Food and Drug Administration, if it is required. Now, again, that IDE is essentially human clinical trials.

C, obtain a premarket approval, something called a PMA, a clearance from the FDA if it is required. Now, what that involves, and, again, new terms, but a PMA is essentially the most difficult and broadest approval from the FDA to market a medical device. It comes with the fact that you're going to have to do human clinical trials to get that approval. The PMA is in contrast to something called a 510(k), which we have put on this chart to introduce you to these terms. The 510(k) is a process where a device company can go to the FDA and say we want an approval because there already exists something out there that is doing what we're doing. We can essentially shortcut the process of having to go with premarket approval, the PMA. The evidence will show that while Medtronic filed a 510(k) on its screw/tether, it always understood that it was going to have to do human clinical trials.

The other piece of the vocabulary related to the FDA is something called an HDE. That is a humanitarian device exemption. It basically relates to an attempt to try to pursue a very small part of the market and obtain an approval from the FDA to put the product in that segment of the market. Again, there is no guarantee with a 510(k) or with the HDE that you don't have to do a human clinical trial and IDE. What the contract says in B and C is that Medtronic would prepare and file and obtain approval for IDE

and PMA if it were required by the FDA.

The next promise that they make is that they would provide worldwide marketing, sales and distribution of the licensed product after receipt of U.S. and foreign regulatory approvals to market and sell the licensed products. E, they would financially support the efforts by Dr. Braun relating to development and evaluation, both technical and clinical evaluations of the licensed products, and then they reference that the estimated costs and expenses of such ongoing support are set forth in Exhibit C.

F, financially support travel by Dr. Braun to national and international surgeon meetings in order for him to present research relating to the licensed products as reasonably requested.

Now, I would also like to talk about the part of this language that says if it is required by FDA. The evidence will prove without question that Medtronic always knew and understood that the FDA was expected to require IDE and human clinical trials. The contract itself recognizes that. The evidence that they always understood that begins with Exhibit B to the contract, which indicates that by 2001 in the fourth quarter Medtronic is projecting that it will determine the regulatory strategy and file with the FDA, and they say expect IDE PMA. Then the contract indicates in their projections that by 2002 they would begin human trials

if approved by the FDA.

You're also going to hear from Medtronic witnesses who will acknowledge that they always knew human clinical trials would be required. You're going to hear by video deposition from Jon Serbousek, who was a former division president of Medtronic, and you're going to hear from Troy Drewry, who was an engineer that worked on the project from Medtronic, and you're going to hear from Medtronic's regulatory experts, Tim Ulatowski and Karen Becker, all of whom are going to acknowledge that they always knew that clinical trials would be required.

That reality is confirmed in documents. I would like to refer you to several, Exhibit 116, Exhibit 117, Exhibit 113 and Exhibit 114. Looking at one of these as an example, Exhibit 116, this is a plan that was prepared December 5th of 2000, not very long after the license agreement was entered into, and it indicates anchor and tether loop need IDE.

Dr. Braun brought this lawsuit in 2010, and the question is what did Medtronic do over the ten year period from 2000 to 2010 to pursue the required FDA approvals for IDE and PMA. The evidence will be not a thing. They never filed a single application with the FDA on behalf of Dr. Braun.

What Medtronic will say is that what they did do

is in 2002 they filed a 510(k) permission related to the screw/tether, not Dr. Braun's device, but something that they will argue is similar enough. They will argue that they sought 510(k) as essentially a steppingstone, that if we can get 510(k) for the screw-tether, then it would serve as a steppingstone and we could got the approval for Dr. Braun.

I would like to refer to a regulatory time line, and this will be undisputed, and it is essentially important evidence that you will be presented with and that you will need to consider. I will refer you to these five documents that tell the regulatory time line story. The evidence will be that on October 4, 2002, three months after Medtronic had filed the 510(k) on the screw/tether, and that is essentially the hopeful shortcut to a marketing approval from the FDA, that the FDA told Medtronic what it already knew, which is set forth in Exhibit 554. Quote, clinical data is necessary. That is what they already knew. That is what they expected and that is what they were told. And that no tether device to treat scoliosis in children would be allowed without human clinical trials.

Then what happened? Medtronic responded to the FDA on February 24, 2003. This is Exhibit 556. Here is Medtronic's response. Quote, should the agency disagree with our position and maintain that a clinical study is

required, we, as a company, would have trouble justifying the cost of a clinical study. The letter is signed by Richard Treharne, who is a Ph.D. and vice president of regulatory affairs for Medtronic.

Here is that letter. The evidence will be that that statement to the FDA is in direct conflict with section 3.2 of the license agreement that says Medtronic shall do a PMA and IDE if FDA requires it. It is also inconsistent with Medtronic's representation in Exhibit B of the agreement that it expects IDE and PMA.

The evidence will be that after taking the position that the cost of the IDE could not be justified, that Medtronic considered going back to the FDA, and they prepared an agenda to do that and Medtronic has indicated that they may discuss that agenda with you in their opening argument. What they have proposed in that agenda was to have Dr. Braun talk to the FDA. What the evidence will show is that Medtronic simply never went back to the FDA. They never came back to Dr. Braun and even discussed with him what they were going to do.

Instead, Medtronic made the decision to not go back to the FDA. Thereafter, and the evidence will be undisputed, that Medtronic was not in communication with the Food and Drug Administration for seven years. Not that they just didn't file an application, they were not in

communication with the FDA concerning any type of tethered device.

Medtronic's regulatory experts have tried to qualify that testimony by saying that, well, we did go back to the FDA in 2009, so only one year prior, and with respect to what is called the Shilla device. Shilla is a completely different product, and you'll hear some testimony about it, and it is essentially a combination of a fusion and fusionless device, both, that, again, is no less intrusive than a fusion surgery. It involves opening up the back and a partial fusion of the spine. Other than that caveat, that Medtronic went back in 2009, the evidence will be that for six or seven years no communications with the FDA regarding the tether device.

The evidence of Medtronic's true intent at the time it signed its agreement and committed to Dr. Braun to do human clinical trials is revealed in documents, including the February letter that I just showed you. It is also revealed in other documents. I would refer you to Exhibit 116. This is, again, only nine months after the contract is signed. This is dated December 5th of 2000. This is their strategic planing meeting. This document indicates and acknowledges that they need an IDE, but what do they say about their intent? That is on page 7 of that presentation. They don't say we're going forward. They ask themselves the

question, not that we shall do it, but does the market opportunity justify the cost?

The evidence will show that Medtronic had other only if caveats and qualifications to its firm commitments to Dr. Braun. Paragraph 3.1 of the license agreement says plainly that Medtronic shall conduct research and development necessary to commercialize a licensed product.

Now, the evidence will show that that commitment is contrary to their documented business plans. The evidence of their true intention is contained in, again, documents. I would refer you, again, to Exhibits 116 and 117. Look at Exhibit 117. This is nine months after the license agreement. Rather than complete research and development firmly to proceed with development of Dr. Braun's device, Medtronic says that instead it is going to choose. It is going to either take the bone anchor and tether, or it is going to take the screw/tether and it is going to decide which is the best tether option before it goes to human clinical trials and conducts an IDE. That statement of intent by Medtronic, the evidence will show, is inconsistent with the license agreement and Medtronic's firm commitment to Dr. Braun that they would conduct clinical trials if required, not if it decides it likes the screw/tether better than the bone anchor.

The evidence will also show that Medtronic was

going to pay for an IDE only if it decided that it was going to pursue the bone anchor and not the screw/tether. Looking at Exhibit 113, which is the March 27, 2001 development plan, Medtronic, again, the evidence will show, reveals its true intent. It is going to pick the best tether option, and it then indicates how it is going to go about making that evaluation.

Do you have the next slide?

This same document, the action plan, shows that Dr. Braun is to receive a five percent royalty in association with that product, while the screw/tether, which is a screw that Medtronic has already developed, has a zero percent royalty.

Now, the evidence will be, and you will hear evidence from Medtronic's own employees, that a five percent royalty is a significant royalty. You'll hear testimony from Mr. Serbousek, a former division president of Medtronic, and he has negotiated license agreements, and he did not negotiate this contract with Dr. Braun, but what he will say is that a five percent royalty represents an innovation, a first to market opportunity. The evidence will also show that up through 2005 Medtronic considered Dr. Braun to be its scientific head, and those are their words, of fusionless deformity.

I need to now talk about the patents and what

happened and the evidence you'll hear with respect to the patents. The documentary evidence will show what Medtronic did not do to pursue its obligations under the license agreement relating to patents.

Let's go back one.

Its commitments under the license agreement were that it would file patent applications on Dr. Braun's behalf. It further agreed to use sound and reasonable judgment in making patent prosecution decisions. Now, here are the documents, and neither side can indicate that this is not a complicated issue and a complicated story, but these are the key documents. These show you essentially what happened.

On November 5th of 2001 Medtronic filed a provisional patent application on behalf of Dr. Braun. That is Defendant's Exhibit 1501. That application lists as the inventors Dr. Braun and Medtronic employees Mr. Drewry, Mr. Molz and Mr. Sherman. Now, that document, 1503, the first patent application, consistent with an invention disclosure document signed by Dr. Braun and Medtronic, shows and depicts that the tether can be either a straight tether or a loop tether.

Then on May 2nd of 2002, and this is Exhibit 363, Medtronic filed the non-provisional patent application on behalf of Dr. Braun and its employees. Those applications

will become something called the 121 patent. We're going to use these shorthands, and that is just the number that is associated with the patent that Medtronic obtained for Dr. Braun. That is Exhibit 435.

On August 14th of 2002, and this is Exhibit 649, Medtronic filed a patent application that the parties will call the 497 patent, with the inventors listed as Medtronic employees, Sherman and Molz, not Dr. Braun. That patent describes surgical methods that Dr. Braun will testify he disclosed to Medtronic in his written disclosure and in an oral communication that he had with Mr. Sherman. His communication with Mr. Sherman concerned the fact that Dr. Braun's idea, after coming up with the initial surgical method, he said why don't we do this and let's do this in a two-stage surgery. Let's allow these anchors to become fixed in the bone and grow, and that way we can obtain even greater surgical correction on the table. Once they are fixated, then you can apply greater compressive forces and bring them together before you put the tether around them.

This invention that Medtronic obtained relates to precisely that idea. It also includes aspects of the disclosure made by Dr. Braun to Medtronic. It includes a flexible tether on the convex side of the spine. It includes, and it is not limited to this, but it includes a fruscoconical shaped hollow bone anchor with fenestrations

to obtain fixation.

It also describes applying compressive forces to bring the anchors together. It discloses the use of these methods and devices to correct scoliosis. The evidence will show that by obtaining and filing the 479 patent, which is, again, Exhibit 649, Medtronic misappropriated and took for itself Dr. Braun's ideas. The evidence will also show that on January 13, 2004, that Dr. Braun and Medtronic were told by the patent office that they had to elect either the device parts of their patent or the methods. You'll hear evidence that this is not unusual. The patent office will indicate both to Medtronic and to Dr. Braun, both in the context of Dr. Braun's patent and other patents that Medtronic has, to elect one or the other. You can still go back to the patent office and obtain the other, but you do it in phases.

On January 13th they are put to that election. The election is made and Medtronic says to Dr. Braun let's pursue the device. We'll do the method later. They explain to Dr. Braun that the advantage of doing it that way, that there is a silver lining and a real advantage, which is that if you do it in two phases that you essentially extend the life of the patent, because you now have two different patented things.

They go ahead and they say that they will pursue

the device now and the method later, and they tell Dr. Braun why they want to do that, and they then abandon the method. They never file anything to pursue Dr. Braun's method, which is the most valuable aspect of what he disclosed to Medtronic. The evidence will show that election.

The evidence will also show that exactly three weeks later on March 4th of 2004, and this is Exhibit 494, Medtronic filed a patent application on behalf of its employees, Mr. Drewry and Mr. Molz, and that application will become a family of patents that begins with Exhibit 368, which is the 379 patent. That application is March 4th, 2004, Exhibit 494. The patent they obtained is Exhibit 368, the 379 patent.

The evidence will show that after electing not to pursue the methods, that Medtronic sought and obtained a patent on Dr. Braun's idea of bringing compressive force to those anchors, bringing them together and attaching the flexible tether while they are in their compressed state to allow correction of scoliosis.

The last issue that I want to address in terms of the story and the evidence that you will hear are the issues related to what Medtronic did or didn't do to fulfill this contract. I have already covered most of it. The answer to be supplied by the evidence is they did very little. The evidence will show that they did literally nothing from a

regulatory point of view. The evidence will be that they were not in communication with the FDA after they tried to get a 510(k) that they knew was going to result in the FDA telling them what they already knew, which was human clinical trials would be required.

On the patent front the evidence will show that they patented only a small piece of Dr. Braun's intervention, and, instead, took for itself other aspects of his invention and put it into its own patents filed in the names of its employees.

With respect to the overall development, the evidence will show that Medtronic, and you'll hear from its witnesses a number of I don't remember and I don't recall, but what the evidence will show is that they paid $275,000 over a six-year period while Dr. Braun engaged in animal research related to his invention. He conducted that research at the University of Utah and elsewhere.

The evidence will show that despite repeated requests by Dr. Braun to proceed, that Medtronic continued, and in its own internal words the project was in phase zero. The evidence of Medtronic's nonperformance includes Exhibit 122, which is a Braun disclosure status document prepared in 2006. The document reveals a series of admissions by Medtronic concerning its lack of contract performance. At page 3 of that PowerPoint presentation Medtronic presents

what it has done. Prepare the development work plan. What it is referring to is that it had one attached as Exhibit B to the initial contract on April 1st of 2000, and we know that it did that.

To financially support ongoing research efforts. We know it paid $275,000. Financially support travel. That is what Medtronic indicates it has done.

Now, let's look at the next slide which indicates what it has never done. Incomplete. Never executed a development work plan in accordance with the proposed development plan set forth in Exhibit B. It has never prepared and filed and conducted an investigational device exemption for the Food and Drug Administration if it is required, which it was. It has never obtained premarket approval clearance with the FDA if it is required, which it was. It never provided worldwide marketing, sales and distribution of licensed product after receiving appropriate U.S. and foreign regulatory approvals to market and sell licensed products.

Let's look at the next slide which shows the activities that they did perform. Completed. What this is is this is their projection, Exhibit B, and it is showing from what we predicted and the dates that we would complete these things and what did we actually do. Well, they have gone through activities that were projected to be complete

by 2001 in the first quarter.

Now, let's look at the next slide.

This is what they didn't do. These are the things that were to be done in the original projections by the second quarter of 2000, the third quarter of 2000, and the fourth quarter of 2000. They didn't select the best tether option. They didn't make a go, no-go decision.

Let's look at the next slide.

What this shows is that essentially they didn't do anything beyond those few things that they projected would be done in the earliest years under their projection. Remember that they had indicated in their projection that by 2002 in the first quarter they would be conducting human clinical trials. The evidence will show that Dr. Braun was also continuously misled about what Medtronic had done and what Medtronic intended to do going forward.

The evidence will show that Dr. Braun's relationship with Medtronic fundamentally changed in 2005 and in 2006, although, Dr. Braun, was, the evidence will show, kept in the dark about important aspects of that relationship. For example, in 2005 Dr. Braun made a decision as a surgeon, a medical decision to stop using Medtronic products. The evidence will show that Medtronic's response to that was to take Dr. Braun -- he is no longer the head of their team of fusionless, and he is not even on

their list of what they call KOLs, another abbreviation, key opinion leaders. These are the surgeons who are involved in this area and he is not on the team anymore.

The evidence will show that Medtronic had been assembling its new team, unbeknownst to Dr. Braun. The evidence will also show that by 2006 Medtronic was no longer investing in a company called Axial. Up to that point Axial had been funded by Medtronic, and it had one of its representatives who sat on the board of directors of Axial. We're going to hear from Dr. Braun and from James Ogilvie, two physicians, who at the time were at the University of Utah and involved with Axial.

Axial was a company that was doing genetic research to try to determine which of these children and adolescents would end up with the curvature of the spine and having to have a fusion surgery because they would continue to progress, and trying to predict in which of those that would happen. The evidence will show that once Axial became funded by a Medtronic competitor, that Medtronic's firm shall commitments to Dr. Braun became even less important to Medtronic. The evidence will show that Medtronic, as a matter of business practice, simply was not willing to fulfill its contract obligations to Dr. Braun so long as he was involved with a company that Medtronic now perceived as a competitor.

The evidence of Medtronic's misrepresentations to Dr. Braun will be presented in documents. I would refer you to Exhibit 497. This is a document dated February 8th of 2006. It is a PowerPoint presentation. Medtronic is, again, trying to indicate to Dr. Braun that we are working on your project and we are proceeding we are continuing and we have not given up on this idea and we're going forward. If you look at what they show to Dr. Braun under bone anchor project plan, they specifically say in this 2006 document, regulatory submission, prepare and submit 510(k), receive decision from FDA. That is what Dr. Braun was told.

The evidence will show that if you compare Exhibit 497 with 123, which is a document dated the same day, and it has the same title and the same update, and let's look at what they indicate internally. On the FDA plan, the bone anchor project plan, regulatory submission, prepare and submit 510(k) for Eclipse screw, receive decisions from FDA, currently not resourced.

The evidence will show that by December 9th of 2006, which is an important date, and you're going to hear from Medtronic about what happened on December 11th of 2006, so this is two days before, that Medtronic has a fusionless think tank. In that think tank you can see that it has a new team of surgeons. It is Dr. Skaggs, Dr. Lenke, Dr. McCarthey and Dr. Oswald. This is two days before Dr. Braun

sends an e-mail to Medtronic.

The e-mail, which Medtronic will discuss with you, is an e-mail from Dr. Braun to Medtronic and he is reasonably indicating his concerns. He is not happy. He wants some answers. You need to look at that document and look at what it actually says. The first line of Dr. Braun's response, and, again, at this time he will testify that he has no idea that they have already assembled their own fusionless team, and he is operating under the assumptions based on that PowerPoint I showed you before that Medtronic is still going forward and that they are going to help him. His first thing is to say thank you for your recent efforts to rejuvenate my fusionless project at MSD. I am hopeful that with a renewed commitment by MSD we'll be able to make some progress in the development of these devices. He concludes the e-mail by saying so how do we move forward? He proposes that there be individuals at Medtronic assigned to the project to proceed. Dr. Braun was misled and the evidence will show that he was misled about Medtronic's continued and ongoing commitment to proceed.

In light of the overwhelming evidence that will be presented that Medtronic didn't perform the license agreement and its firm promises, the question becomes what evidence is Medtronic going to present to defend its action and lack of conduct. Medtronic will attempt to prove that

Dr. Braun waited too long to file his complaint. The problem with that is that even as late as November 23rd, 2008, which is Exhibit 147, Medtronic continued with its misstatements to Dr. Braun, including on that day it stated to him that it, quote, continues to comply with both agreements in all respects. The evidence will show that it was not until Medtronic offered to return to Dr. Braun only a small portion of his invention that he discovered Medtronic's true intent and its true motivation. At that point they were no longer willing to return his invention. They were willing to return only a piece.

Prior to that time Dr. Braun was trying very hard to continue with his development of a fusionless device that he believes very passionately would help children who are suffering from scoliosis. The evidence will show that Dr. Braun in doing so was relying on Medtronic's resources and its continuing and ongoing representations that it would proceed.

Medtronic is also going to raise an issue and argue that Dr. Braun didn't own his invention at the time that it was provided to Medtronic, and that supposedly that invention is owned by the United States Air Force, where Dr. Braun worked prior to the time that he left the Air Force and began at the University of Utah. You'll hear no evidence that the Air Force claims any interest in Dr.

Braun's ideas. You'll hear no evidence that while he was in the Air Force Dr. Braun was working on anything to do with the bone anchor and a tethered device.

To the contrary, what you will hear evidence of is that while in the Air Force Dr. Braun was doing goat and animal studies on the staple device of Medtronic through Medtronic's funding with Medtronic's full knowledge and Medtronic's full permission. The evidence will show that Dr. Braun told Medtronic while he was in the Air Force that he had ideas, and that he had ways in which he thought he could improve upon the staples, which don't have the ability to actively correct the scoliosis curve on the surgical table.

Medtronic's response was to tell Dr. Braun lets solidify those ideas. They sent him literally on the day of his discharge, which is Exhibit 104, they sent him a letter with an invention disclosure book and said, Dr. Braun, write your ideas down, which is what he did.

The evidence will show that Medtronic was completely aware of the process that Dr. Braun went through to come up with the patentable invention, and it never raised any concerns with respect to the Air Force until two or three years after this lawsuit was filed.

The last thing I want to talk to you about is damages. I am going to be very brief, but you'll be

presented with a calculation of Dr. Braun's profits and what he should have earned in royalties under the license agreement and the five percent royalty that was provided to him. The calculation of those damages will be based upon Medtronic's projections of the fusionless market. They will be based upon Medtronic's evaluation of risk and success, including that as of 2013 and 2014 Medtronic still believes, to a high degree of probability, that a tether device can effectively and safely treat adolescent idiopathic scoliosis, and that it can not only treat it, but that it can benefit those adolescents who will not have to have their spines fused and engage in a much less invasive procedure.

The evidence will show that Medtronic continues to believe that that market is extremely profitable when and if Medtronic makes the decision to conduct human clinical trials necessary to complete the development process. Dr. Braun's lost profits calculation is just that, it is an estimate, it is a reasonable estimate and evaluation that will be presented through a qualified damages expert.

Thank you.

THE COURT: Thank you, Mr. Bradshaw.

Why don't we all take a short break. We'll exchange some equipment and you can all freshen up a little bit and we will come back in in about 15 minutes.

(WHEREUPON, the jury leaves the proceedings.)

THE COURT: Anything more, counsel?

MR. JARDINE: No, Your Honor.

THE COURT: Let's be in recess.

Thank you.

(Recess)